AnaptysBio Announces Positive Top-Line Proof-of-Concept Data For ANB020 In Moderate-to-Severe Baseline Adult Peanut Allergy Patients

March 26, 2018

- **46% of adult peanut allergy patients with moderate-to-severe baseline symptoms tolerated 500mg cumulative peanut challenge at 14 days after a single dose of ANB020 compared to zero percent dosed with placebo**
- **Concomitant allergy symptoms, typically overlapping with peanut allergy, occurred in 80% of placebo dosed but only 7% of ANB020 dosed patients**
- **ANB020 was well tolerated and no patients have discontinued from the study**
- **AnaptysBio plans to initiate a multi-dose Phase 2b trial in moderate-to-severe baseline adult peanut allergy patients**
- **Management to host conference call today at 5:00p.m. EDT**

SAN DIEGO, March 26, 2018 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq:ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation, today announced top-line proof-of-concept data from an interim analysis of an ongoing Phase 2a trial in adult patients with peanut allergy. Six of 13 (46%) patients exhibiting moderate-to-severe symptoms during a baseline oral food challenge at enrollment improved peanut tolerance to cumulative 500mg at day 14 after a single dose of ANB020 compared to zero of three (0%) dosed with placebo. Allergic symptoms that typically overlap with peanut allergy were observed in four of five (80%) patients dosed with placebo but only one of 15 (7%) ANB020-dosed patients. ANB020 was generally well-tolerated and all patients remain enrolled in the clinical trial. AnaptysBio plans to continue development of ANB020 in moderate-to-severe baseline adult peanut allergy patients in a Phase 2b multi-dose clinical trial.

“Peanut allergy is a serious medical condition often associated with other food allergies, atopic dermatitis and asthma,” said Stephen Tilles, M.D., Clinical Professor at the University of Washington, Executive Director of Asthma Inc Clinical Research Center, Immediate Past President of the American College of Allergy, Asthma, and Immunology (ACAAI) and an investigator in this Phase 2a clinical trial. “The data from this trial suggest that ANB020 may be a promising new paradigm for peanut allergy patients. Patients suffering from this debilitating condition are motivated to pursue new treatments that provide protection from the life-threatening symptoms of accidental peanut exposure.”

Phase 2a Trial Design
This Phase 2a proof-of-concept trial enrolled 20 adult peanut allergy patients with a clinical history of anaphylaxis. The baseline peanut tolerance of each patient was evaluated at enrollment using a blinded, placebo-controlled oral food challenge (OFC) according to PRACTALL guidelines, where each patient experienced dose limiting symptoms at or before a cumulative 500mg dose of peanut protein. Patients were subsequently randomized on a 3:1 basis to receive a single intravenous 300mg dose of ANB020 or placebo at 14 days following the baseline OFC, and then administered a second OFC at 14 days after dosing. Each OFC was limited to a maximum of 500mg cumulative peanut dose. Symptom severity was adjudicated by an independent, blinded assessor that was not involved in performing the baseline or day 14 OFC.

Interim Analysis
This interim analysis focused on patients with moderate-to-severe baseline symptoms, which is the patient population that AnaptysBio plans to target for future development of ANB020 in adult peanut allergy. Thirteen ANB020 dosed and three placebo dosed patients exhibiting moderate-to-severe symptoms during the baseline OFC were included in the analysis, while two ANB020 dosed and two placebo dosed patients with mild baseline symptoms were excluded. The average age and baseline peanut tolerability of moderate-to-severe baseline patients was 31 and 239mg, respectively, which were consistent with the age and baseline peanut tolerance of all 20 enrolled patients.

In patients with moderate-to-severe symptoms at baseline, six of 13 (46%) patients administered a single dose of ANB020 improved peanut tolerance at the day 14 OFC to the maximum tested cumulative 500mg dose, compared to none of the placebo dosed patients. Amongst the patients excluded due to mild baseline symptoms, one ANB020 dosed patient and two placebo dosed patients improved peanut tolerance to the 500mg cumulative dose at the day 14 OFC. Concomitant allergy symptoms, typically overlapping with peanut allergy, including urticaria, pruritus, rhinitis, asthma flares and other nut allergies, occurred in four of five (80%) patients following placebo administration but only occurred in one of fifteen (7%) patients after ANB020 dosing.

ANB020 was generally well-tolerated during the study and all 20 patients remain enrolled with no dropouts. No serious adverse events have been reported and the most frequent treatment-emergent adverse event reported in ANB020 dosed patients was headache in four of fifteen patients, of which three were mild cases and one was moderate severity, while the most frequently reported adverse events in placebo dosed patients were mild and moderate severity allergy-related events in four of five patients.

"We are encouraged by the rapid improvement in peanut tolerance and favorable safety profile observed to date in this study following a single dose of ANB020," said Hamza Suria, president and chief executive officer of AnaptysBio. "We believe ANB020 has the potential to prophylactically protect moderate-to-severe baseline adult peanut allergy patients from anaphylaxis. In addition, we believe ANB020 may address multiple concomitant allergic conditions irrespective of the specific allergens involved."

The company plans to report detailed data from this trial at a future medical conference following study completion.

AnaptysBio plans to continue development of ANB020 in a randomized, double-blinded, placebo-controlled subcutaneously-administered multi-dose Phase 2b trial in moderate-to-severe baseline adult peanut allergy patients.

Conference Call & Webcast Information
The AnaptysBio management team will host a conference call and live webcast with slides with the investment community today, Monday, March 26th, 2018, at 5:00pm EDT to discuss the information in this press release.
When: March 26, 2018, 5:00pm EDT
Dial-in: (833) 696-8361 (Domestic), (430) 775-1625 (International)
Conference ID: 2289207

The live webcast and accompanying slides can be accessed under the investor relations section of AnaptysBio's website at www.anaptysbio.com. A replay of the conference call will be archived under the investor relations section of the AnaptysBio website for 30 days shortly after the call.

About ANB020
ANB020 is an antibody that potently binds and inhibits the activity of interleukin-33, or IL-33, a pro-inflammatory cytokine that multiple studies have indicated is a central mediator of atopic diseases, including atopic dermatitis, food allergies and asthma. Following completion of a healthy volunteer Phase 1 trial of ANB020, AnaptysBio has demonstrated proof-of-concept for ANB020 in a 12-patient Phase 2a trial of moderate-to-severe adult atopic dermatitis and in the aforementioned 20-patient placebo-controlled Phase 2a trial in adult peanut allergy patients. Enrollment is ongoing in a 24-patient placebo-controlled Phase 2a trial of ANB020 in severe adult eosinophilic asthma patients where top-line data are anticipated in the third quarter of 2018. During the first half of 2018, AnaptysBio plans to initiate a placebo-controlled multi-dose Phase 2b clinical trial of subcutaneously-administered ANB020 in 200-300 moderate-to-severe adult atopic dermatitis patients where data is anticipated in 2019.

About AnaptysBio
AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The company's proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody (ANB020) for the treatment of moderate-to-severe adult atopic dermatitis, moderate-to-severe adult peanut allergy and severe adult eosinophilic asthma; its anti-IL-36R antibody (ANB019) for the treatment of rare inflammatory diseases, including generalized pustular psoriasis and palmo-plantar pustular psoriasis; and a portfolio of checkpoint receptor agonist antibodies for the treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated, which have demonstrated efficacy in an animal model of graft-versus-host disease. AnaptysBio's antibody pipeline has been developed using its proprietary somatic hypermutation (SHM) platform, which uses in vitro SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology partnership with TESARO and an inflammation partnership with Celgene, including an anti-PD-1 antagonist antibody (TSR-042), an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody (TSR-033), which are currently under clinical development with TESARO, and an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in the clinic with Celgene.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the results of, and timing of the release of data from, our clinical trials; the applicability of interim results to the results of later trials, the potential of ANB020 as a prophylactic therapeutic for the treatment of moderate-to-severe adult peanut allergy patients; our ability to launch future clinical trials and the success of our partnership with TESARO and Celgene. Statements including words such as "plan," "continue," "expect," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize its product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Contact:
Monique Allaire
THRUST Investor Relations

617.895.9511
monique@thrustir.com

Chelcie Lister
THRUST Investor Relations
910.777.3049
Chelcie@thrustir.com

Source: AnaptysBio, Inc.